Section 5: 510(k) Summary

APR 0 7 2014

Product: Speed Triad™

Submitter Information

BioMedical Enterprises, Inc.
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Date Prepared: April 3, 2014

Classification name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Classification:	Class II
Product Code:	JDR
Common/Usual Name:	Bone Staple
Proprietary Name:	Speed Triad

Intended Use:

The Speed Triad is indicated for:

Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Substantial Equivalence:

The Speed Triad is substantially equivalent to the predicate BME Speed Shift™ cleared in K124022, predicate OSSplate™ cleared in K993714, labeled as the Memograph® Staple, and predicate K070598 (SmartToe). The K993714 predicate also includes an intended use of fixation of proximal tibial metaphysis osteotomy and fixation of soft tissue to bone (anterior cruciate reconstruction) which is not included in this submission.

Device Description:

The Speed Triad is a nitinol implant that comes in a range of sizes for use in extremity bone fragment fixation, osteotomy fixation, and joint arthrodesis of the hand and foot. The implant is delivered to the operating room in an "open" state in a constraining plastic inserter. The implant is then released from the inserter and transformed by ambient temperature and body heat after insertion, and contracts to a "closed" and compressive state. The implants do not require any external heating; they are completely transformed at room temperature.

The Speed Triad incorporates design changes from the Speed Shift. The design is changed to include a third leg to provide additional fixation. Importantly, the Speed Triad uses the same raw material as the predicate Speed Shift and the same manufacturing process (heat treatment, surface treatment, and passivation).

A second predicate is used for comparison of mechanical and corrosion properties of the Speed Triad. Because the Speed Triad implants are more similar shaped to the predicate OSSplate implants than the Speed Shift implants, BME has used the OSSplate to show substantial mechanical and corrosion resistance equivalence to a similar-sized implant.

The table below summarizes the technological characteristics of the Speed Triad and the predicate devices.

Technological Characteristics Comparison to the Predicate Devices[1]

Product Name:	Speed Triad	Predicate Speed Shift (K124022)	Predicate OSSplate (K993714)
Raw Material:	Nitinol, per ASTM F2063-12	Nitinol, per ASTM F2063-12	Nitinol, per ASTM F2063-12
Bridge Lengths (mm):	18, 20, and 25	15 and 20	15
Leg Lengths (mm):	10, 12, and 15	20	6, 8, and 10
Cross-section Dimensions (mm):	1.25 x 1.50 (Double Leg)/ 1.25 x 1.80 (Single Leg)	1.8 x 2.0 (Leg)	1.20 x 1.50 (Leg)
Barbs:	Barbs on the legs	Barbs on the legs	Smooth legs
Heat Source:	Fully transformed at room temperature	Fully transformed at room temperature	OSSforce electrical heating unit
Surface Finish:	Mechanical tumbling, acid cleaning, and chemical passivation.	Mechanical tumbling, acid cleaning, and chemical passivation.	Mechanical tumbling only.
Patient Contacting Materials:	Nitinol Grey PC #5816 SS 17-4 SS-303	Nitinol Grey PC #5816 SS 17-4 SS-303	Nitinol SS 17-4 SS-303
Storage:	Sterile packaged stored at room temp until used.	Sterile packaged, stored at room temp until used.	Sterile packaged, stored at room temp until used.

[1] – Predicate SmartToe not shown, but it is a nitinol extremity fixation device used for comparison of corrosion resistance only.

Performance Bench Testing:
Standard ASTM F564-10 (2010) was used to compare the pull-out strength of the Speed Triad to the predicate OSSplate. Specimens of all three sizes of the Speed Triad were used and compared to a comparably sized predicate OSSplate. The results showed that the Speed Triad has substantially equivalent pull-out resistance than the predicate OSSplate implant.

Standard ASTM F564-10 (2010) was used to compare the mechanical strength of the new Speed Triad to the predicate OSSplate. Specimens of all three sizes of the Speed Triad were used and compared to a similar sized predicate OSSplate. The results showed that the Speed Triad implants achieved substantially equivalent bending stiffness when compared to the predicate OSSplate.

Standard ASTM F2129-08 was used to compare the corrosion resistance of representative samples of the new Speed Triad to the predicate OSSplate. We also have used a secondary predicate for corrosion resistance, the SmartToe (K070598). Test results demonstrate the substantially equivalent corrosion resistance of the Speed Triad compared to the predicate OSSplate and SmartToe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 7, 2014

BioMedical Enterprises, Incorporated
Mr. Joe Soward
Director, Quality Assurance and Regulatory Affairs
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K133844
Trade/Device Name: Speed Triad™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: March 11, 2014
Received: March 14, 2014

Dear Mr. Soward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Speed Triad™

Indications for Use

The Speed Triad™ is indicated for:

Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices